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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,227	11/26/2001	Alan M. Fogelman	407T-899210US	9958
22798	7590	03/10/2004	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			CRIARES, THEODORE J	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/994,227

Applicant(s)

FOGELMAN ET AL.

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.
- 4a) Of the above claim(s) 16-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/11/03</u> | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-81 ARE PRESENTED FOR EXAMINATION

Applicant's election without traverse of Group A, claims 1-12, 14 and 15, in Papers received November 20, 2003 is acknowledged.

Applicants request that claims 1-15 be examined as to the generic invention of claim 1 is deemed proper. The examination of these claims were accordingly examined for the generic invention as claimed in claim 1. i.e., the ameliorating one or more symptoms of atherosclerosis in a mammal, said method **comprising** administering to said mammal a phospholipid in an amount sufficient to ameliorate one or more symptoms of atherosclerosis.

Claims 16-81 are withdrawn from consideration.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 is indefinite since it is not clear if the phospholipid is a complex with the claimed fatty acids or the claimed fatty acids are additional agents in the formulation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-8, 10-12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsia et al. (5,231,090).

Hsia et al. Teach at column 1, line 55 to column 3, line 23 applicants' claimed known compounds, i.e. phosphatidylcholine and phosphatidylserine when administered in effective amounts treats atherosclerosis. At column 1, lines 55-60 teaches that phospholipids were administered intravenously and topically and resulted in the resolution of atherosclerotic lesions. Examples II and III illustrate the administration of phospholipids to humans are effective in treating phospholipids. See claims 11 and 12.

Claim 2 drawn to a phospholipid that is a phospholipid that inhibits upregulation of anMKP-1 gene is deemed to be inherent in the teachings set forth above since applicant may have determined a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

The phospholipids, phosphatidylcholine, phosphatidylserine, (applicants' claim 3 are taught at column 3, lines 56-63)

Claims 6 and 7 read on the teachings at column 2, lines 56-63 wherein it is taught that the claimed phospholipids can be combined.

The mode of administration as claimed in claims 8 and 10 are taught in the reference as injection and in the form of a gel liquid etc.

Claim 1 is open ended, therefore claim 14 and 15 are anticipated under 35 U.S.C. 102(b) as stated above since the claims as drawn read on the administration of a phospholipid..

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsai et al. in view of Bertilli (4,684,520). Hsai et al. teach as stated above the administration of phospholipids in the treatment of atherosclerosis. The difference between this reference and the applicants' claim 9 is that Hsai does not teach the oral administration of said phospholipids. However, one of ordinary skill in the art would be motivated to

administer said phospholipids orally since Bertilli at column 2, lines 47 to column 3, line 19 teach that phospholipids can be administered orally.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bertilli (4,684,520). Bertilli teaches at column 5, lines 44-56 that certain phospholipids are useful in the treatment of atherosclerosis. However, one of ordinary skill in the art would have been motivated to use an analogue of 1,2-dimyristoyl-*sn*-glycero-3-phosphocholine of applicants' claim 4 since at column 1, lines 19-26 it is disclosed that cholineglycerophospholipid, an analogue of applicants' claimed active agent is useful in the preparations of the invention taught therein and use in the treatment of atherosclerosis. One of ordinary skill in the art would have been motivated to use an analogue of applicants' claimed compound to treat atherosclerosis with the phospholipid taught by the reference with a reasonable degree of expectation to succeed.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsai et al. in view of Aviram et al. . Hsai et al. teach as stated above the administration of phospholipids in the treatment of atherosclerosis.

The difference between applicants claim 13 and the cited reference is that applicants claim the addition of a statin to the formulation to be administered. However, one of ordinary skill in the art would have been motivated to incorporate a statin in the formulation to treat atherosclerosis since Aviram et al teach at column 1, lines 14-21 and column 5 lines 9-25 that statins when administered to a patient can treat atherosclerosis.

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072

(CCPA 1980):

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-277, 126 USPQ 186, 188 (CCPA 1960).

As this court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in the prior art. "

In this application it would have been prima facie obvious to administer a phospholipid and a statin to treat atherosclerosis.


The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." *In re Gorman*, 933 F.2d 982, 18 USPQ 2d 1885, (Fed. Cir. 1991). In view of the above rejection it is deemed that the evidence presented has established a prima facie case of obviousness. is presented.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Theodore J. Criares
Primary Examiner
Art Unit 1617

TJC
3/8/04